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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,759	05/30/2001	David S. Terman		8812

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EXAMINER	
HOLLERAN, ANNE L	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/870,759	TERMAN, DAVID S.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 13, drawn to mammalian cell receptors that bind tumor associated lipids, or lipid binding proteins, classified in class 530, subclass 350.

II. Claim 2, drawn to tumor associated lipids, classified in class 562, subclasses 2, 3 or 400.

III. Claims 3-6 and 25, drawn to mammalian cells selected from the group consisting of T-cells, NKT cells, antigen presenting cells, dendritic cells, fibroblasts and macrophages, classified in class 435, subclass 325.

IV. Claim 7-10, 26, 29 and 30, drawn to methods for producing a tumoricidal immunocyte population comprising contacting tumor associated lipids with immunocytes having inactivated or deleted receptors for immuno suppressive lipids, classified in class 514, subclass 558.

V. Claims 11 and 12, drawn to methods for treating cancer by administering a lipid binding molecule, classified in class 514, subclass 2.

VI. Claims 14-24, drawn to constructs comprising a virus in combination with a superantigen, classified in class 435, subclass 235.

VII Claims 27 and 28, drawn to compositions comprising a lipid raft conjugated to a superantigen, classified in class 424, subclass 283.1.

2. The inventions are distinct, each from the other, for the following reasons:

Inventions I-III, VI and VII are patentably distinct products.

The mammalian cell receptors of group I and the tumor associated lipids of group II are patentably distinct inventions for the following reasons: mammalian cell receptors are protein products, and tumor associated lipids, are structurally distinct molecules. Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the lipids are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. There is search burden also in the non-patent literature. The tumor associated lipids as presently claimed encompass more than the specific lipid molecules that may bind to the claimed receptor molecules. Furthermore, the tumor associated lipids read on lipids that are isolated and used in products such as cosmetics. As such, it would be burdensome to search the inventions of groups I and II together.

The mammalian cell lipid receptors of group I and the mammalian cells of group III are patentably distinct for the following reasons: mammalian cell receptors are protein products and mammalian cells are compositions of matter.

While some of the mammalian cells that are within the scope of the claims may express lipid receptors, the inventions of group III encompass cells where the lipid receptor is absent. Therefore, the inventions are structurally distinct.

Furthermore, searching the inventions of group I and group III would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and a mammalian cell require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and

unobviousness of the protein. However, such a search is not required to identify the cells of group III.

The lipid receptors group I and the virus constructs of group VI are patentably distinct for the following reasons: the lipid receptors are protein products and the virus constructs are compositions of matter. Furthermore, the two inventions do not appear to share any structural features in common, and do not appear to be related by function. Therefore, the lipid receptors and virus constructs are patentably distinct.

The lipid receptors and virus construct inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group I and group VI would impose a serious search burden since a search of the lipid receptors of group I is would not be used to determine the patentability of the virus construct of group VI, and vice-versa.

The lipid receptors group I and the lipid raft compositions of group VII are patentably distinct for the following reasons: the lipid receptors are protein products, whereas the lipid raft compositions comprising a super antigen are compositions of matter. Furthermore, the two inventions do not appear to share any structural features in common, and do not appear to be related by function. Therefore, the lipid receptors and lipid raft compositions are patentably distinct.

The lipid receptors and lipid raft composition inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group I and

group VII would impose a serious search burden since a search of the lipid receptors of group I is would not be used to determine the patentability of the virus construct of group VI, and vice-versa.

The tumor associated lipids of group II and the mammalian cells of group III are patentably distinct for the following reasons: tumor associated lipids are individual molecular products, whereas mammalian cells are compositions of matter.

The tumor associated lipids of group II do not appear to be associated with the specifically claimed mammalian cells of group III. Therefore, the inventions are structurally distinct. Furthermore, the patentability of the tumor associated lipids as individual products is not determined by their possible association with tumor cells, but by individual structural features, such as their molecular structure. Thus, the determination of patentability of the tumor associated lipids will be, in part determined by a search that goes beyond any association with tumor cells

The searching the inventions of group II and group III together would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A lipid and a mammalian cell require different searches. A structure search is necessary for a determination of novelty and unobviousness of the lipid. However, such a search is not required to identify the cells of group III.

The tumor associated lipids of group II and the virus constructs of group VI are patentably distinct for the following reasons: the tumor associated lipids are individual

molecular products, whereas the virus constructs are compositions of matter. Furthermore, the two inventions do not appear to share any structural features in common, and do not appear to be related by function. Therefore, the lipid receptors and virus constructs are patentably distinct.

The tumor associated lipids of group II and virus construct inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group II and group VI would impose a serious search burden since a search of the tumor associated lipids of group II would not be used to determine the patentability of the virus construct of group VI, and vice-versa.

The tumor associated lipids of group II and the lipid raft compositions of group VII are patentably distinct for the following reasons: the tumor associated lipids of group II are individual molecular products, whereas the lipid raft compositions comprising a super antigen are compositions of matter. It is not disclosed that the lipid raft compositions share structural features with any of the individual tumor associated lipids. Therefore, the tumor associated lipids of group II and lipid raft compositions of group VII are patentably distinct.

The tumor associated lipids of group II and lipid raft compositions of group VII have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group II and group VII would impose a serious search burden since a search of the tumor associated lipids of group II is would not be used to determine the patentability of the virus construct of group VI, and vice-versa.

The mammalian cells of group III and the virus constructs of group VI are patentably distinct for the following reasons: the mammalian cells of group III are structurally distinct from the virus constructs of group VI. Furthermore, the two inventions do not appear to share any structural features in common, and do not appear to be related by function. Therefore, the mammalian cells of group III and virus constructs are patentably distinct.

The mammalian cells of group III and virus construct of group VI have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group III and group VI would impose a serious search burden since a search of the tumor associated lipids of group III would not be used to determine the patentability of the virus construct of group VI, and vice-versa.

The mammalian cells of group III and the lipid raft compositions of group VII are patentably distinct for the following reasons: the mammalian cells of group III are structurally distinct from the lipid raft compositions comprising a super antigen. Therefore, the mammalian cells of group III and lipid raft compositions of group VII are patentably distinct.

The mammalian cells of group III and lipid raft compositions of group VII have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group III and group VII would impose a serious search burden since a search of the mammalian cells of group III is would not be used to determine the patentability of the virus construct of group VI, and vice-versa.

Inventions IV, and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of producing a tumoricidal immunocyte population (group IV), and the method of the method of treating cancer (group V) are unrelated as they comprise distinct steps and utilize different products, demonstrating that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. For example, the method of group IV uses tumor associated lipids in combination with immunocytes having inactivated lipid receptors, whereas the method of group V uses a protein product that is a lipid binding molecule, where the product is administered to a mammal. Therefore, each method is divergent in materials and steps. For these reasons the Inventions IV and V are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups IV and V have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups IV and V together.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cell receptors of group I can be used in a process to purify

and isolate lipid molecules that bind to the receptor, which is a process that is materially different from the process of group V, a method for treating cancer in a mammal.

Searching the inventions of Groups I and V together would impose serious search burden. The inventions of Groups I and V have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the searches for the cell receptors of group I and for the method of treating cancer in a mammal using lipid binding protein are not coextensive . Group I encompasses specific protein molecules which are limited to cell receptors, whereas the search of group V requires a search of all proteins that may bind to lipids in addition to a text search for methods of treating cancers.

Inventions I and IV are unrelated because the product of group I is not used or otherwise involved in the process of group IV.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of group II, tumor associated lipids, would be searched broadly as lipid molecules, regardless of any association with tumors. Lipids are known to be components of cosmetics and nutrient compositions and therefore, may be used in processes that are materially different from the process of producing a tumoricidal immunocyte population.

Searching the inventions of Groups II and IV together would impose serious search burden. The inventions of Groups II and VI have a separate status in the art as shown by their

different classifications. Moreover, in the instant case, the search for the lipids and the method of producing a tumoricidal immunocyte population using a lipid are not coextensive. Group II encompasses molecules which may have nothing to do with tumors, but are structurally the same as tumor associated lipids, and therefore the search would not be coextensive with a search for a method for producing a tumoricidal immunocyte population.

Inventions II and V are unrelated because the product of group II is not used or otherwise involved in the process of group V.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even when the requirement is traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
September 29, 2004

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER
9/30/2004